Exhibit G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1 TVT CASES**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF CHRISTOPHER ERIC RAMSEY, M.D.

I. BACKGROUND AND QUALIFICATIONS

My curriculum vitae is attached. After completing my undergraduate degree at Dartmouth College, I attended medical school at the Medical College of Ohio. I completed my residency in urology at the University of Oklahoma Health Sciences Center in 2002. I have been board certified in urology since 2004. I am a member of The American Urological Association and a fellow of the American College of Surgeons.

I have extensive and ongoing experience in the diagnosis and treatment of female and male urinary incontinence and other pelvic disorders. This experience includes taking histories, performing physical exams, and ordering and conducting diagnostic testing, including urodynamic testing. I am familiar with the potential risks and complications associated with both non-surgical and surgical treatment of continence disorders. Additionally, I co-manage female patients with Pelvic Organ Prolapse (POP).

I have performed various types of surgeries for the correction of stress urinary incontinence, including native tissue repairs, cadaveric, and porcine fascial slings or grafts and the use of synthetic material slings, including those made of Prolene. I will testify about why I transitioned to synthetic mid-urethral slings for the treatment of Stress Urinary Incontinence (SUI).

I have also participated in professional education from Ethicon for TVT, TVT-Obturator ("TVT-O"), and TVT-Secur ("TVT-S") as a student and have proctored others in TVT-O and TVT-S. I have participated in long-term follow up on my own patients who have undergone various types of SUI surgery. I regularly attend continuing medical education conferences, some of which deal with surgery for stress urinary incontinence and other pelvic floor disorders. I also have experience with models and cadaver specimens. I have a thorough understanding of the mechanism and safety profile of Prolene mesh slings.

I have performed approximately 1,000 surgeries to correct SUI, approximately 300 utilizing TVT-O, 25-50 utilizing TVT, and 400 utilizing TVT-S. In my experience, I have found the TVT products to be safe and effective and durable for my patients. Since 2012, I now use a single incision mini-sling called the MiniArc Precise by Astora and have performed approximately 150 cases.

II. MATERIAL REVIEWED

I have reviewed information pertinent to this litigation, including medical records, depositions, deposition exhibits, and some company documents. I was either already familiar with, or had reviewed, published medical literature and position statements. I have also reviewed some Plaintiff expert witness disclosures.

My opinions will be expressed to a reasonable degree of medical or scientific probability or certainty.

III. DISCLOSURE OF OPINIONS

A. Overview of Opinions

I will talk about pelvic organ prolapse and the types of urinary incontinence, including stress, urge, and mixed incontinence, and the frequency with which these conditions occur, the risk factors for them, and the negative impact that they can have on a woman's quality of life. I will discuss how the risks for female urinary incontinence increase with vaginal childbirth, advanced age, smoking, diabetes, COPD, obesity, and genetics. I will describe how female urinary incontinence is a major public health concern. I will discuss how the changed anatomy and physiology of pelvic floor disorders guides a surgeon in recommending the appropriate options to the patient for the treatment for POP and SUI.

I will discuss the non-surgical treatment options for stress and mixed urinary incontinence. This will include the advantages, disadvantages, risks, ease of use and effectiveness of medications, behavior modification, physical therapy, and pessaries. I will testify that surgery, overall, is more effective for the treatment of SUI than non-surgical treatment[1] and that the overwhelming majority of women, after weighing their options and risks, choose surgery as their primary treatment for SUI. The risk profile of mesh is acceptable and the benefits outweigh the risks.

I will discuss the surgical treatment options for stress urinary incontinence, including whether the options are affected by the concomitant presence of pelvic organ prolapse. The discussion will include the different techniques and materials available over the years. The discussion will also include the risks and effectiveness of the various techniques and materials. The discussion will also include how, over time, surgeons publishing in the medical literature proved the effectiveness of synthetic mid urethral slings as equal to or better than native tissue repairs, with less risk overall. I will express my opinion that the mid-urethral slings – including the TVT products – have been and continue to be surgical options relied upon by reasonable and

[1] American College of Obstetricians and Gynecology, Practice Bulletin Summary, 126 (5), November 2015.

prudent surgeons. According to the medical literature, the American Urology Association, and the American College of Obstetricians and Gynecologists, TVT is the gold standard for incontinence surgery.[2]

Ethicon's family of TVT products are made of Prolene. Chemically, Prolene consists of polypropylene plus the addition of proprietary additives. Polypropylene has been widely used as a suture material for more than 50 years and is demonstrated to be safe and effective in the human body. I am aware that there are mechanically versus laser cut mesh products. There is no difference in laser-cut versus mechanically cut mesh from a clinical standpoint. Data shows they perform the same. The data from 1998 to 2006 (before laser-cut mesh was available) is consistent with the data from 2006 to the present (when laser-cut mesh was available), showing similar efficacy and safety in hundreds of studies, randomized controlled trials ("RCT"), and reviews. The data show no difference in exposures over time. I will testify about how the mesh integrates safely and effectively into the body.

B. Urinary Incontinence

The involuntary leakage of urine, or urinary incontinence, is a common problem that impacts women of all ages. Although reported incidence rates vary by study, best estimates are that involuntary leakage of urine affects 10-55% of women on a regular basis. The various types of urinary incontinence, as well as a few relevant terms, are defined below.

- Stress urinary incontinence (SUI) refers to accidental leakage of urine which occurs with activity like coughing, sneezing, jumping, standing, or lifting heavy objects.

- Urge urinary incontinence (UUI) refers to sudden urge to urinate followed by leakage of large amounts of urine.

- Mixed incontinence refers to patients with symptoms of both SUI and UUI.

- Overactive Bladder (OAB) refers to a collection of the above-described symptoms as well as nocturia (the need to pass urine at night).

- Intrinsic Sphincteric Deficiency (ISD) is a severe form of SUI. It is defined as Low Leak Point Pressure. ISD is measured with urodynamic testing.

- Drainpipe urethra implies a urethral lumen that does not close, even at rest, with lack of mobility of the urethra.

Known risk factors for stress urinary incontinence include: age, pregnancy/childbirth, obesity, genetic predisposition/ethnic heritage, menopausal status, diabetes, kidney disease, smoking, chronic coughing, and other factors. Urinary incontinence negatively affects quality of life for patients with the condition. Women who suffer from urinary incontinence see low scores

[2] AUGS/SUFU Position Statement, American Urogynecology Society January 2014.

on Quality of Life (QOL) questionnaires and may experience depression. 25-50% of women with SUI experience sexual dysfunction.

Women who suffer from SUI likely have weak ligament support and weak pelvic muscles and may have increased abdominal pressure, inherently weak periurethral tissues, or a loss of elasticity of the urethra. Hypermobility, or an excursion of the urethral angle greater than 30 degrees, with strain or cough implies weak ligamentous support of the urethra.

Treatment options for SUI include behavioral treatments, non-surgical treatments, and surgical procedures. Behavioral methods include weight loss, smoking cessation, control of chronic cough, decreasing fluid intake, and timed voiding. Non-surgical treatments include pelvic muscle (Kegel) exercises, biofeedback devices or intravaginal electrical stimulation, an intravaginal incontinence pessary (a device worn in the vagina that externally compresses the urethra), urethral caps, urethral inserts, and possibly timed voiding. Procedures or surgeries to treat SUI include injection of periurethral bulking agents, mid-urethral prolene mesh slings, cadaveric fascia or autologous fascia pubovaginal slings, or abdominal retropubic urethropexy, including the Marshall-Marchetti-Krantz Procedure and the Burch procedure.

C. Historical Treatment of SUI

Before the late 1990s, the most common procedures used to treat SUI were the Marshall-Marchetti-Krantz procedure, the Burch procedure, and the pubovaginal sling procedure.

The Marshall-Marchettie-Krantz ("MMK") Procedure is also known as the retropubic suspension or bladder neck suspension surgery. This procedure involves general anesthesia, requires a 2-6 day hospital stay, can lead to bony or other pelvic complications, and has inferior long-term efficacy. For these reasons, the MMK procedure is not the procedure of choice today.[3]

The Burch procedure originated in the 1960s. Initially, this procedure involved attaching the paravaginal fascia to the arcus tendineus. Eventually, surgeons began attaching the paravaginal fascia to Cooper's ligaments because these were believed to provide more secure fixation points and less chance of infection as seen with the prior MMK procedure. The Burch procedure is not a treatment for ISD, as success rates have been unacceptably low in this population. Instead, it is indicated only for genuine stress urinary incontinence ("GSUI"). The Burch procedure requires an abdominal incision, is time-consuming, and requires a prolonged rehabilitation. Because of the significant post-operative morbidity, voiding difficulty, de novo

[3] Wu JY et al. (2010) Surgical therapies of female stress urinary incontinence: experience in 228 cases. *Int Urogynecol J;* 21:645-649; Chaliha C, Stanton SL (1999) Complications of surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 106(12):1238-45.

pelvic organ prolapse, pain, and delayed failures, the Burch procedure has also lost popularity with surgeons.[4]

The pubovaginal sling procedure places graft material directly under the urethra and attaches it to the connective tissue (fascia) of the abdominal muscles. The success rate of the sling is good, but long-term success rates may show some decline. In the SISTEr trial at seven years, the urinary continence rate (no reported leakage by the patient) was only 13% for the Burch procedure and 27% in the pubovaginal sling group.[5] However, both procedures showed decline in the long-term follow-up and 27% of patients required treatment for postoperative urge incontinence. In comparison to the Burch, the fascial sling has a higher rate of UTI, urge incontinence, voiding dysfunction, and the need for surgical revision to improve voiding, such as urethrolysis to relieve urethral obstruction. The increased efficacy but greater morbidity of the fascial sling is echoed in other systematic reviews and in my own practice and experience.[6]

D. Transition to Mesh to Treat SUI

The Gynecare TVT is made from Prolene (polypropylene) mesh. Surgeons have used polypropylene mesh as a permanent human implant for decades. The first polypropylene meshes were developed and used by hernia surgeons in the 1950s. Ethicon started using Prolene (polypropylene and certain extracts) in sutures in the 1960s. Prolene sutures have been used for various procedures including cardiovascular repairs, plastic surgery, hernia repairs, and pelvic floor repairs. Ethicon used that same material to develop Prolene mesh for hernia surgery in the early 1970s. The inflammatory response associated with Prolene was widely known long before Prolene was used to treat SUI.

In the early 1990s, there was no standard, generally accepted surgical repair to treat SUI. Instead, surgeons were using various methods. Each method had high recurrence rates, significant morbidity, substantial complications, long hospital stays, and substantial recovery times. For these reasons, Dr. Ulf Ulmsten, a physician in Sweden, was working on a new way to treat SUI.

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[4] Wu JM et al. (2011) Trends in inpatient urinary incontinence surgery in the USA, 1998-2007. *Int Urogynecol J* 2011, 22: 1437-43; Nager CW et al. (2012) A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med* 366(21):1987-97; Chughtai BI et al. (2013) Midurethral sling is the dominant procedure for female stress urinary incontinence: analysis of case logs from certifying American urologists. *Urology* 92(6):1267-71; Suskind AM et al.(2013) Effectiveness of mesh compared with nonmesh sling surgery in Medicare beneficiaries. *Obstet Gynecol* 2013, 122(3):546-52; Rogo-Gupta L et al. (2013) Trends in the surgical management of stress urinary incontinence among female Medicare beneficiaries, 2002-2007. *Urology* 82:38-42.; Wu C-J et al. (2014) The surgical trends and time-frame comparison of primary surgery for stress urinary incontinence, 2006-2010 vs 1997-2005: A population-based nation-wide follow-up descriptive study. *Int Urogynecol J* 25:1683-91.

[5] Richter HE, et al. (2012), Patient related factors associated with long-term urinary continence after Burch colposuspension and pubovaginal fascial sling surgeries. *J Urology* 188(2):485-89; Albo ME et al. (2007) Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med* 356: 2143-55.

[6] Richter (2012), supra; Albo (2007) supra; Brubaker L et al. 5-year continence rates, satisfaction and adverse events of Burch urethropexy and fascial sling surgery for urinary incontinence, *J Urology* 187:1324-30; Rehman H, et al. Traditional suburethral sling operations for urinary incontinence in women. *Cochrane Database Syst Rev.* 2011 Jan 19.

Dr. Ulmsten, along with Dr. Peter Petros, began placing several different types of mesh under the mid-urethra in the 1990s.[7] The surgeons experimented with, among others, Prolene, Gore-Tex, and mersilene. 8-10% of the patients rejected the Gore-Tex and mersilene tapes.[8] Prolene demonstrated the most promising results. Eventually, Dr. Ulmsten began placing meshes loosely around the urethra, a procedure that became the TVT procedure. Unlike the Burch, MMK, and other procedures, this new procedure did not chronically kink the urethra.[9]

Dr. Ulmsten's first trial concluded in 1996 and included 75 patients with a two-year follow-up. [10] Of those 75 patients, 84% (63 patients) were completely cured and an additional 8% (6 patients) were significantly improved. None of these patients experienced significant intra- or postoperative complications, defective healing, or rejection of the sling.

During the mid-1990s, Ethicon and Dr. Ulmsten began to discuss Dr. Ulmsten's approach to correct SUI. In 1997, Ethicon began to sell TVT in Europe. In 1998, several surgeons, including Dr. Ulmsten, carried out a prospective randomized study with six centers in Scandinavia to test the safety and efficacy of the TVT device. The study included 131 patients suffering from SUI. Of those 131 patients, 91% (119 patients) were cured and another 7% (9 patients) were significantly improved.[11]

Since 1998, the literature has substantially supported TVT's safety and efficacy. In fact, more than 80 randomized controlled trials have assessed the TVT and approximately 1,000 studies have addressed the TVT mesh.[12]

E. Gynecare's TVT

Women with SUI, who have failed non-operative measures, are candidates for surgical treatment of SUI. Polypropylene mesh slings, such as the TVT, are the most common surgical treatment for SUI.

Polypropylene mesh slings for the treatment of female SUI has been studied extensively. The studies demonstrate minimal morbidity compared with alternative surgeries such as Burch, MMK, or PVS. Advantages of the sling procedure include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, reduced voiding dysfunction, higher long-term success rates, and low complications.

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[7] Petros PE, Ulmsten UI (1993), An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol Suppl*;153: 1-93; Ulmsten U, et al., A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998;9(4):210-3; Petros P. (2015) Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond: Ulf Ulmsten Memorial Lecture. *Int Urogynecol J* 26(4):471-76.

[8] 1996 Ulmsten.

[9] Ulmsten U, et al. (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 7:81-86; Ulmsten U, et al. (1995) Intravaginal slingplasty (IVS): An ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol* 29:75-82.

[10] Ulmsten U, et al. (1996) Supra.

[11] Ulmsten U (1998) A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J*, 9:210-213.

[12] A systematic review of patient-years of experience in prospective randomized controlled trials (RCTS) in incontinence, ETH.MESH.07246690-719; CER TVT Family of Products, ETH.MESH.10178882- 10179216.

Although mesh-related complications can occur following polypropylene sling placement, the rate of these complications is acceptably low. The rate of reoperation for voiding dysfunction and exposure has been consistently reported in 2-5% of patients up to ten years post-operatively.[13] Furthermore, most sling-related complications such as urinary retention, UTI, and pelvic pain occur with transvaginal mesh and non-mesh procedures alike. Finally, surgery due to pain occurs in less than 1% of patients per these data.

1. *TVT Has Been Widely Studied*

There are over 150 Randomized Controlled Trials with TVT and TVT-O establishing their efficacy and safety. There are numerous long term studies with both TVT and TVT-O which also establish their efficacy. These studies demonstrative objective and subjective cure rates for 80-95% of patients.[14] To put this into perspective, data on the Burch procedure for 190

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[13] Welk B et al. (2015) Removal or revision of vaginal mesh used for the treatment of stress urinary incontinence. *JAMA Surg* 150(12):1167-75; Unger CA et al (2015). Incidence of adverse events after uterosacral colpopexy for uterovaginal and posthysterectomy vault prolapse. *Am J Obstet Gynecol* 212:603. E1-7. Schimpf MO, et al. (2014) Sling surgery for stress urinary incontinence in women: a systematic review and meta-analysis. *Am J Obstet Gynecol* 211: 71.e1-27; Laurikainen E et al. (2014) Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. *Eur Urol* 65(6):1109-14; Jonsson Funk M, et al. (2013) Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse. *Int Urogynecol J* 24:1279-85; Svenningsen R, et al. (2013), Long-term follow-up of the retropubic tension-free vaginal tape procedure 24:1271-78; Nguyen JN, et al. (2012) Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. *Obstet Gynecol* 119:539-46; Ogah J, et al. (2009). Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women (review). *Cochrane Review* 2009, Issue 4; Novara G, et al (2008) Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. *Eur Urol* 53(2):288-308.

[14] Nilsson CG et al. (2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. *Int Urogynecol J* 19:1043-47; Liapis A, et al. (2008) Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. *Int Urogynecol J* , 19:1509-12; Olsson I et al. (2010) Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. *Int Urogynecol J* 21:679-83; Liapis A et al. (2010) Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. *Eur J Obstet Gynecol Reprod Biol* 148:199-201; Angioli R, et al. (2010) Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. *Eur Urol* 48:671-77; Groutz A, et al. (2011) Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. *J Minim Invasive Gynecol* 18(6):726-29; Aigmueller T et al. (2011) Ten year follow-up after the tension-free vaginal tape procedure. *Am J Obstet Gynecol* 205:496; Groutz A, et al. (2011) Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure. *J Womens Health* 20(10):1525-28; Cheng D, Liu C (2012) Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol* 161(2):228-31; Heinonen P, et al. (2012) Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. *Int J Urol* 19(11):1003-09; Serati M et al.(2012) Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. *Eur Urol* 61:939-46; Nilsson CG et al. (2013), Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* 24:1265-69; Svenningsen R (2013) Long-term follow-up of the retropubic tension-free vaginal tape procedure. *Int Urogynecol J* 24:1271-78; Serati M, et al. (2013) TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. *Eur Urol* 63:872-78; Laurikainen E et al. (2014) supra; Athanasiou S et al. (2014) Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? *Int Urogynecol J* 25:219-25.

women at 14 years revealed significant urinary incontinence in 56% of patients. Only 19% of these women were completely cured.[15]

Dr. Carl Nilsson published 17-year data for the TVT in 2013.[16] Dr. Nilsson reported data for 46 women who were followed postoperatively for 17 years. Of those 46 women, 91.3% (42 women) were objectively cured. These women showed no clinically significant contracture, no tape rejection, and only one mesh exposure, which was asymptomatic and due to vaginal atrophy in an elderly patient who was satisfied. This study demonstrated the TVT is safe and effective after 17 years.

In 2010, Dr. Ingegerd Olsson, et al., published the clinical results of 85 women who were implanted with TVT and reached 11.5 years of follow-up. In this study, 147 women were assessed with an objective cure rate of 84%. 94% of patients were satisfied with the surgical result. Of note, 2.7% of patients experienced bladder perforations, 1.4% experienced urethral injury, and 7.2% experienced urinary tract infections. There was one healing defect at two months post-op and no late tape rejection. At follow-up, none of the patients had voiding difficulties. The authors' conclusion was that the procedure was safe and effective after more than 10 years.[17] I agree with this conclusion.

Dr. Maurizio Serati, et al., published another long-term study on TVT in 2012. This group followed 63 patients for 10 years. The report begins by aptly stating that "[r]etropubic and transobturator tension-free midurethral slings (TVT and transobturator tape TVT-O) represent the most effective and popular procedures for the surgical treatment of stress urinary incontinence (SUI) and are currently considered the gold standard." In this study, the 10-year subjective, objective, and urodynamic cure rates were 89.7%, 93.1%, and 91.4%, respectively. Bladder perforation occurred in two cases (3.8%) intraoperatively. In both situations, the bladder lesion was identified during the operation and the tape was promptly removed and replaced. No severe bleeding or other intraoperative complications occurred. No postoperative complications requiring surgical intervention occurred. During the final follow-up visit, voiding difficulties were reported in two patients. Notably, no patient required tape release or resection during the 10-year follow-up. No significant POP, vaginal, bladder, urethral erosion, or de novo dyspareunia were noted in the remaining 58 patients.[18]

Data analyzing the safety and efficacy of TVT consistently demonstrate that the device and procedure are safe and effective. TVT has been and continues to be the gold standard for treatment of SUI. No other device or SUI surgery has been studied as extensively as TVT. Contrary to Plaintiffs' experts' claims, TVT's long term results clearly demonstrate that complications associated with TVT do not increase over time.

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[15] Kjolhede P. (2005) Long-term efficacy of Burch colposuspension: a 14-year follow-up study. *Acta Obstet Gynecol Scand*, 84:767-72.

[16] Nilsson CJ et al. (2013), Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J 19:1043-47*.

[17] Olsson I, et al. (2010), Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. *Int Urogynecol J* 21:679-83.

[18] Serati M, (2012) Supra.

The TVT is the most effective procedure for women because it provides a well-known and well-established treatment for SUI. It is minimally invasive and safer when compared to alternative procedures, including the Burch procedure and autologous pubovaginal slings. This is demonstrated in the data of several meta-analyses (Cochrane review), systematic reviews, and guidelines.

2. *TVT is the Safest Procedure*

I am aware that Plaintiffs' experts have opined that procedures including anterior plication, needle suspension, Marshall-Marchetti-Krantz (MMK), and open and laparoscopic Burch colposuspension are safer alternative procedures when compared to the TVT. These procedures are considered native tissue repairs, but do require the use of a permanent suture such as Prolene or Gore-Tex.

I discussed the MMK procedure, the Burch procedure, and PVS earlier in this report. It is my opinion that anterior plications, needle suspension (such as the Raz procedure), paravaginal defect repair, and the MMK should not be offered as treatment options for SUI. The success rates are unacceptably low and the benefits do not outweigh the risks. My opinion is consistent with the 2013 National Institute for Health and Care Excellence (NICE) guidance.[19]

F. Alleged Complications Associated with TVT

Plaintiffs' experts claim that TVT is associated with several complications, including infection, inflammation, cytotoxicity, contraction, degradation, and cancer. Each of those alleged complications are addressed in turn below.

1. *Infection*

Ethicon, through the TVT IFU, warns of the possibility of infection when implanting a TVT device. Infections are no more common with TVT mesh than they are with native tissue repairs. Further, because the TVT mesh has large pores and is made from polypropylene mesh, any infection can usually be treated without removal of the mesh.

The IFU warns that in some cases of persistent infection, mesh removal may be necessary. Removal of foreign bodies is not limited to TVT. For example, removal may be necessary with non-absorbable sutures, as even sutures can become contaminated. Again, infection is uncommon following incontinence surgery and is not necessarily a result of the mesh but instead of the patient's wound healing characteristics.

Rates of infection from MVS surgery, as reported in the literature, are very low.

2. *Inflammation*

Plaintiffs' experts have suggested that there may be an inappropriate inflammatory response associated with the TVT. In my practice, I have not experienced an inflammatory

[19] National Institute for Health and Care Excellence, Urinary incontinence: The management of urinary incontinence in women, Sept. 2013 at guidance.nice.org.uk/cg171.

response with TVT. Nor is it demonstrated in the literature from peer-reviewed urology, urogynecology, or gynecology journals.

It is known and accepted that there will be some level of inflammatory response with any foreign body. Contrary to Plaintiffs' experts' suggestion, the inflammatory response associated with TVT is beneficial because it promotes anchorage and adds structure and support to the mesh and thus, enhances efficacy and durability. In my experience, this degree of inflammation is not clinically harmful or significant in that it rarely causes chronic pain, infection or adversely affects adjoining structures.

Furthermore, chronic inflammation and chronic inflammatory cells can be seen in vaginal tissue in the absence of mesh or another foreign body. The presence of chronic inflammatory cells does not mean that those cells are active. Plaintiffs' experts' claims that the mesh is continuously subjected to peroxides and other substances produced by chronic inflammatory cells are not accurate. If their contention was true, we would not see the superior cure, efficacy, and tolerability rates that have been shown in the literature and in my personal experience. There would essentially be death of the tissues around this theoretical peroxide-exposed area with tissue necrosis in all TVT patients.

3. *Cytotoxicity*

Any claim that TVT is cytotoxic in women is not credible. The long-term studies and data do not show cytotoxicity, and their results are contrary to Plaintiffs' experts' theories. If the mesh were cytotoxic, the tape would be rejected in all of the women and the tissue would die, becoming necrotic. This is not reflected in the medical literature and would be after all the years of study, if it was true. Instead, the vast majority of patients have demonstrated efficacy with low complications.[20]

4. *Contraction*

Contrary to Plaintiff's experts' contention, TVT mesh does not curl, contract, or experience pore collapse when implanted as directed in the IFU. The sheath protects against tissue trauma, protects the mesh as it slides through the tissue, and enables the mesh to keep its shape. The mesh itself does not contract.

TVT's design allows incorporation of tissue and reduces the risk of infection. Scar tissue contracts in any pelvic surgery. If the TVT mesh had significant contracture, it would contract uniformly, chronically elevating the bladder and leaving almost all patients with voiding

[20] In fact, mesh exposure occurs at a rate of approximately 1-3% in TVT patients as earlier noted in the Novara 2008 meta-analysis (1.1% vaginal erosion), Cochrane reviews such as: Ogah J et al. (2011) Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn* 2011, 30(3):284-91; and Ford AA, et al. (2015) Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev* CD006375 (2.1%); Tommaselli G, et al. (2015) Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and meta-analysis. *Int Urogynecol J* 26(9):1253-68.systematic review and meta-analysis of medium and long term complications (Fig. 6, 2.1%) and the 2014 SGS systematic review by Schimpf, et al. (1.4%), supra.

dysfunction. The clinical literature again does not support these propositions. Clinically significant tissue contraction is a rare complication.

5. *Degradation*

Plaintiffs' experts claim that TVT degrades in vivo. Clinical evidence, including my own clinical experience, establishes that TVT mesh does not degrade. If it does, any such degradation does not lead to a clinically significant effect. Instead, long-term clinical studies show lasting success and low to no late-term complications.

From a clinical standpoint, I have never seen the TVT mesh degrade or cause any clinical effect. I have not witnessed any gross evidence of mesh degradation on surgical revision cases. If somehow the mesh did microscopically degrade, there has been no clinical effect. Moreover, I am aware of no literature showing any clinical effect of degradation and Plaintiffs' experts point to none.

6. *Cancer*

Finally, there is no reliable scientific information to support Plaintiffs' experts' claim that polypropylene can cause cancer or sarcoma. Medical literature is devoid of reports of tumors related to the implantation of surgical-grade polypropylene for midurethral slings.

Hundreds of millions of individuals have been implanted with polypropylene mesh in various forms over many years.[21] Despite this, there is no evidence linking polypropylene to cancer in humans. Recently, Dr. Courtenay Moore and others published data on 2,361 sling procedures. Of those, only two patients (0.0%) were diagnosed with any malignancy during a four year follow-up period.[22] This study demonstrates that there is no association between polypropylene mesh midurethral sling placement and cancer.

TVT is comprised of the same polypropylene that has been used for decades. There is no statistically significant risk of cancer associated with TVT. There was no need for Ethicon to warn of this alleged risk in the TVT IFU.[23]

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[21] AUGS & SUFU, Frequently Asked Questions by Providers—Mid-urethral Slings for Stress Urinary Incontinence. (available at http://www.augs.org/p/bl/et/blogaid=194); Dwyer PL and Riss P (2014) Carcinogenicity of implanted synthetic grafts and devices. *Int Urogynecol J* 25(5):567–568.

[22] Moore C, et al (2014), Is There an Association Between Polypropylene Midurethral Slings and Malignancy? *Female Urology* 84 (4), 2014.

[23] Moalli P, et al (2014), Polypropylene mesh: evidence for lack of carcinogenicity. *Int Urogynecol J* DOI 10.1007/s00192-014-2343-8; King AB, et al. (2014) Current controversies regarding oncologic risk associated with polypropylene midurethral slings. *Curr Urol Rep* 15:453; Sunoco MSDS; AUGS & SUFU, Frequently Asked Questions by Providers—Mid-urethral Slings for Stress Urinary Incontinence. (available at http://www.augs.org/p/bl/et/blogaid=194); King AB et al. (2014), Is there an association between polypropylene MVS and malignancy? *Urology* 84:789-792.

G. Official Guidelines from Governmental Agencies or Medical Societies Regarding SUI surgery and Slings

Several governmental agencies have published guidelines addressing SUI surgery and slings. Those guidelines are summarized below.

1. *American Urogynecologic Society and Society of Urodynamics and Female Urology*

In January 2014, the American Urogynecologic Society (AUGS) and the Society of Urodynamics and Female Urology ("SUFU") released a joint position statement strongly advocating the use of synthetic midurethral slings in the treatment of Stress Urinary Incontinence in women. The key points of the statement are:

- Polypropylene material is safe and effective as a surgical implant.
- The monofilament polypropylene mesh [midurethral sling] is the most extensively studied anti-incontinence procedure in history.
- Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.
- The FDA has clearly stated that the polypropylene [midurethral sling] is safe and effective in the treatment of SUI.

The statement concludes that the midurethral sling procedure is "the most important advancement in the treatment of SUI in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence." I am in agreement with the statement.

On March 26, 2013, AUGS published their "Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders." I agree with their conclusions:

- "Any restriction of mesh slings for the treatment of stress urinary incontinence is clearly not supported by any professional organization or the FDA."
- "Full−length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery."
- "In a recent study involving 53 expert urologists and Urogynecologists (of whom >90% were fellowship trained) and who could select among many surgical options, the full-length synthetic midurethral sling was the preferred option in 93% for the surgical treatment of primary stress incontinence."

On March 12, 2014, AUGS and SUFU released Frequently Asked Question (FAQ) documents for patients and providers on mesh midurethral slings for SUI. Some of the significant commentary in the provider FAQ's include that "currently available mid-urethral slings are composed of macroporous, knitted, monofilament polypropylene, sometimes known as 'Type I' meshes… As an implant for the surgical treatment of SUI, macroporous, monofilament polypropylene has demonstrated long-term durability, safety, and efficacy for up to 17 years."

In response to the question: "Does the [midurethral sling] mesh made of polypropylene degrade over time?," AUGS/SUFU stated that "[p]olypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants. In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very high-magnification images that show portions of some explanted synthetic meshes with 'cracked' surfaces. These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature related to polypropylene mesh repairs. Prospective studies have followed patients with implanted mid-urethral slings for 17 years and show excellent durability and safety of the procedure."

My analysis of the literature also leads me to the same conclusion. I am aware that the experts for the Plaintiff also claim that the mesh is cytotoxic or can cause sarcomas and cancer. As explained above, I do not believe that the clinical literature supports these claims and I have not seen evidence of degradation, cytotoxicity, malignant transformation or cancer in my clinical practice.

2. *International Continence Society ("ICS")*

In July 2013, ICS published a fact sheet titled "A Background to Urinary and Faecal Incontinence." The fact sheet concluded that:

- "Worldwide, midurethral slings compromised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands."

- "The long−term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA."

I agree with these conclusions.

3. *American Urological Association ("AUA")*

In November 2011, AUA published a "Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence." This statement concludes that:

- "Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries."

- "Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling operations as well."

- "It is the AUA's opinion that any restriction on the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."

The AUA updated this position statement in October 2013, and now state that "[m]ultiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years." Further, there is "no significant increase in adverse events observed over this period of follow-up." Finally, the position statement confirms that synthetic slings are not only an "appropriate" surgical choice for the surgical treatment of SUI but that they offer "less morbidity than conventional non-mesh sling techniques."

In 2009, the AUA published an update to its "Guideline for the Surgical Management of Female Stress Urinary Incontinence." The update evaluated the different surgical treatment options and recognizes midurethral slings like TVT as a first line treatment option. This update shows operative and subjective complications for "Slings – Synthetic at Midurethra" without prolapse as follows: 1% of patients reported pain, 0% reported sexual dysfunction, and 2% reported voiding dysfunction.[24] Meanwhile, patients with "Autologous Fascia" slings without Bone Anchors reported pain at 10% and sexual dysfunction at 8%.[25] Finally, 6% of patients who underwent the Burch procedure reported pain, 3% reported sexual dysfunction, and 10% reported voiding dysfunction at 10%.[26]

4. *Food and Drug Administration ("FDA")*

On March 27, 2013, the FDA published "Considerations about Surgical Mesh for SUI," concluding: "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year."

I am aware of FDA's Public Health Notifications relating to transvaginal mesh. Although these notifications initially included prolapse mesh and mesh slings, the second notification excluded meshes for SUI. This is consistent with the relevant medical literature and the standard of care. In 2013, the FDA published the update on SUI slings and found that the TVT was safe and effective, as had been done by the FDA advisory panel. Further, despite legal issues pertaining to transvaginal mesh, mesh slings remain an integral component of my practice as well as the practices of most pelvic surgeons. I feel confident recommending these products to women in my practice.

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[24] American Urological Association, Appell RA, et al. Update to the Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update, at p. 773.

[25] 2009 Updated to the Guideline for the Surgical Management of Female Stress Urinary Incontinence at p. 771.

[26] 2009 Updated to the Guideline for the Surgical Management of Female Stress Urinary Incontinence at p. 770.

5. *National Institute for Health and Care Excellence ("NICE") Guidelines*

The following is taken from the NICE guidelines website as of March 2014. The National Institute for Health and Care Excellence produces guidelines that govern the United Kingdom's health care system. According to the website, "the quality standards are a concise set of prioritized statements designed to drive measurable quality improvements within a particular area of health or care." These guidelines are at times more advanced and more stringent than U.S. guidelines and incorporate evidence based practice as well as cost effective measures.

According to the NICE guidelines, when offering a synthetic mid-urethral tape procedure, surgeons should:

- Use procedures and devices for which there is current high quality evidence of efficacy and safety.
- Use a device manufactured from type 1 macroporous polypropylene tape.
- Consider using a tape colored for high visibility, for ease of insertion and revision.
- Not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI.

In a footnote to the first point, the NICE guideline specifies that it "only recommends the use of tapes with proven efficacy based on robust RCT evidence. However, technological advances are frequent, therefore the choice of tape should include devices that are shown in future clinical trials to have equal or improved efficacy at equal or lower cost. At the time of publication (September 2013) the following met the Guideline Development Group criteria: TVT or Advantage for a 'bottom-up' retropubic approach; TVT-O for an 'inside-out' transobturator approach; or Monarc and obtryx halo for an 'outside-in' transobturator approach."

There are other organizations, including:

- The British Association of Urological Surgeons ("BAUS") – "Synthetic Vaginal Tapes for Stress Incontinence" (December, 2012);
- European Association of Urology ("EAU") - EAU Guidelines on Surgical Treatment of Urinary Incontinence (September 17, 2012); and
- Society of Gynecologic Surgeons ("SGS").

In addition, we have Guidance from Medical Education Guidelines such as:

- American Board of Obstetrics and Gynecology ("ABOG") - www.abog.org - ABOG publishes a "Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery" (FPMRS);

- International Urogynecological Association ("IUGA") - The International Urogynecological Association publishes guidelines[27] regarding the training of FPMRS fellows internationally; and

- American College of Obstetricians and Gynecologists ("ACOG") - The American College of Obstetricians and Gynecologists issued a Committee Opinion in June 2014, in conjunction with the American Urogynecological Society.[28]

H. The TVT Warnings are Sufficient

1. *Instructions for Use*

I am familiar with Instructions For Use (IFU) generally from my experience in the use of medical devices. An IFU accompanying a medical device like TVT provides information to experienced surgeons who have already received training in the surgical treatment of SUI. TVT's IFU is not a comprehensive training guide for the surgical treatment of SUI. Instead, surgeons operating within the standard of care should already be familiar with the risks, potential complications, and benefits associated with pelvic surgery, with or without mesh. The risks associated with these surgeries have been widely publicized in medical literature and at medical conferences. Additionally, the FDA has acknowledged that risks known to be common to pelvic floor surgery (even without mesh) include pain, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuoro-muscular problems and vaginal scarring.[29]

I will testify that the IFU for TVT fairly and adequately informs reasonably prudent surgeons of the indications for TVT, the associated procedure, and the potential risks and complications.

TVT is a medical device, not a separate surgical procedure. It incorporates a technique and a surgical tool used to treat SUI. Ethicon offers professional education programs to physicians who want to learn how to safely and effectively use products like the TVT. The training provided by Ethicon is not required for doctors to order or use the product, and there is no legal certification process involved. Instead, each individual surgeon must determine whether he or she can safely perform stress urinary incontinence procedures, with or without the use of products such as mesh.

2. *Professional Education*

I have been a preceptor for midurethral sling professional education for Ethicon. The professional education curriculum and availability of preceptors and learning opportunities are

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[27] Drutz JP, IUGA Education Committee (2010) IUGA guidelines for training in female pelvic medicine and reconstructive surgery (FPM-RPS). *Int Urogynecol J* 21:1445-53.

[28] ACOG Committee Opinion, No. 603, June 2014. Evaluation of uncomplicated stress urinary incontinence in women before surgical treatment. ACOG.

[29] FDA, Considerations About Surgical Mesh for SUI, April 2, 2013. U.S. Food and Drug Administration http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm downloaded Feb 10, 2016.

well planned, thorough and go well beyond industry standards. Both the surgery and the potential risks are discussed. As a preceptor, I gave didactic lectures, instructed in cadaver labs, proctored physicians who observed my cases in my operating room, observed surgeons on their first cases in their operating rooms, and taught in the IFU.

Reasonably prudent pelvic floor surgeons know the potential risks associated with SUI surgery. The only risk unique to the midurethral sling is mesh exposure. However, wound complications and suture erosions occur with non-mesh SUI surgeries. The risks associated with SUI surgery are taught during training, learned by reading the medical literature and practicing clinically, discussed in professional capacities such at meetings, and studied in connection with professional medical education and our certification process.

3. *Patient Brochure*

I have also reviewed the patient brochures for TVT. A patient brochure is not intended to replace the patient-surgeon relationship and informed consent process. The TVT brochures adequately convey basic information to the lay person and recommend that the patient discuss her condition and options with her surgeon. Only a trained surgeon knows whether TVT is appropriate based upon the particular patient's background, history, and presentation. A surgeon is in the best position to present options to a patient in the exercise of his or her medical judgment. A surgeon's discussion of the potential benefits and risks of various options comes from his or her education, training, experience, discussions with colleagues, attendance at professional meetings, and the medical literature.

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IV. CONCLUSION

I completely agree with AUGS and SUFU that:

- The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence.
- The procedure is safe, effective, and has improved the quality of life for millions of women.
- This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years.
- TVT is the safest option for women seeking surgical repair of their SUI.

I continue to offer synthetic midurethral slings to my patients without hesitation.

Defense counsel and I reserve the right to amend and supplement this disclosure based upon additional discovery in the case, including the depositions of expert witnesses, and developments at trial.

Dated: March 2, 2016